REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, in light of the following remarks and pursuant to 37 C.F.R. § 1.112, are respectfully requested. The amendments made herein are requested solely to expedite the prosecution of what is believed to be allowable subject matter. Applicants specifically reserve the right to file one or more continuation/divisional applications to present claims directed to the canceled subject matter.

Claims 2, 11 and 15 have been canceled without prejudice or disclaimer to applicants filing one or more continuation or divisional applications directed to the subject matter therein.

Claim 1, 11 and 15 have been replaced by claim 19. Claims 3-10 and 12-14 have been replaced by claims 20-30, which are now in appropriate method claim format and depend either directly or indirectly on claim 16.

New claims 31-45 have been added, which claim the composition to be used in the methods of the claimed invention. Support for new claims 31-45 may be found, at the very least, on page 11, line 8, to page 12, line 2, of the specification as filed. No new matter has been added by the present amendment.

Rejection of Claims 1-18 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-18 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner's rejection of claims 1-18, for allegedly being unclear in the use of the phrases "apoptotic bodies" and "apoptotic cells" is respectfully traversed. Applicants understand that the confusion of the language lies in the redundancy of the recitation of both apoptotic cells and apoptotic bodies. The term "apoptotic bodies" embraces "apoptotic cells". Therefore, claims 1 and 3-15 have been replaced by claims 19-30 and the phrase "and/or apoptotic cells" has been removed to delete any redundancy. Applicants submit that this obviates the rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner's rejection of claims 1-18 for purportedly being unclear for failing to set forth any steps involved in the method/process, is respectfully traversed. New claims 19-30 properly reflect that the claimed methods are directed to administration of an effective amount of apoptotic bodies to a mammalian patient suffering from various T-cell-mediated or inflammatory disorders. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner's rejection of claims 1, 2 and 15, for purportedly being unclear as to the metes and bounds of "T-cell-mediated and inflammatory disorders" is respectfully traversed. Newly added independent claims 19 and 31 specifically recite which T-cell-mediated and inflammatory disorders are to be treated by the method of the claimed invention. Applicants submit that this obviates the rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner's rejection of claims 3 and 4, for purportedly being unclear for reciting "cellular" when apoptotic bodies purportedly do not belong to the "cellular"

portion, is respectfully traversed. "Cellular" is defined in Stedman's Medical Dictionary, 26th Edition as "[r]elating to, derived from, or composed of cells." A copy of this reference is attached hereto as Exhibit A. Apoptotic bodies are derived from cells, and therefore would be considered as part of the cellular portion of the liquid suspension. The Dorland Pocket Medical Dictionary definition quoted by the Examiner defines "cellular" as "pertaining to cells," which does not restrict to cellular portions. The term "pertaining to" embraces "derived from." In light of this, reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner's rejection of claim 6 for purportedly being unclear as to the metes and bounds of "extracorporeal treatment" is respectfully traversed. Methods of treating blood cells extracorporeally to produce apoptotic bodies are discussed on page 7, line 25, to page 8, line 30. As stated therein, the claimed invention is not restricted to the use of the methods specifically discussed, and any suitable process known to one of skill in the art for producing apoptotic bodies can be used. It is respectfully believed that one of skill in the art would be well aware of the metes and bounds of the claim, in view of this disclosure. In light of this, reconsideration and withdrawal of this rejection are respectfully requested.

In light of these remarks, applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

Rejection of Claims 1-18 Under 35 U.S.C. § 101

Claims 1-18 have been rejected under 35 U.S.C. § 101 for purportedly being drafted as improper process claims. Claims 1-18 have been replaced to recite proper method claims. In light of this amendment, withdrawal of this rejection under 35 U.S.C. § 101 is respectfully requested.

Rejection of Claims 1-18 Under 35 U.S.C. § 112, First Paragraph

Claims 1-18 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly not being fully enabled by the specification as filed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, the Examiner alleges that the specification is only enabling for the production of apoptotic bodies from murine fibroblasts using sodium butyrate and UV. Applicants respectfully disagree. Each of the means of obtaining apoptotic bodies listed on pages 7 and 8 of the specification as filed are well known to one of skill in the art. Examples of appropriate sources of cells are given at page 7, lines 12-24. A practitioner skilled in the production of apoptotic bodies, using any of the means listed or other means known in the art, would know which cells to use in the methods of the claimed invention for treatment of one of the listed disorders. Furthermore, the practitioner who is skilled in the production of apoptotic bodies would be well aware how to adjust the levels of treatment of the cells, depending on which cell type is used, in order to prevent necrosis.

The question to be asked with regards to 35 U.S.C. § 112, first paragraph, rejections is whether the disclosure is sufficient to enable those skilled in the art to practice

the claimed invention. The specification need not disclose what is well known in the art. Lindemann Maschinenfabrik GMBA v. American Hoist & Derrick Company, 221 USPQ 481, 489 (Fed. Cir. 1984). Methods of preparing apoptotic bodies are well known in the art. Furthermore, it would be within the skill of one in the art to determine which apoptotic bodies are best suited for treating the different disorders recited by the claimed invention. Therefore, the specification, in view of what was known in the art at the time the application was filed, does enable the preparation of the apoptotic bodies used in the claimed invention.

The Examiner also contends that the specification only enables the use of apoptotic bodies for the treatment of mice contact hypersensitivity. Again, applicants respectfully disagree. The contact hypersensitivity model, the subject of Example 1, is a well known, standard method for investigating inflammation, as set out in the references included at page 13, lines 4-11. As noted on page 16 of the specification as filed, the results obtained using the claimed invention for treating contact hypersensitivity indicate that the apoptotic bodies up-regulate the *in vivo* generation of inflammatory Th-2 derived cytokines, such as IL-10 and, perhaps as a consequence, down-regulates inflammatory cytokines, such as TNFγ, IL-6 and IL-12. These inflammatory cytokines are implicated in the various disorders which can be treated with the claimed invention (i.e. psoriasis, rheumatoid arthritis, scleroderma, lupus, diabetes mellitus, organ rejection, miscarriage, multiple sclerosis, inflammatory bowel disease, atherosclerosis and graft versus host disease). Therefore, the successful results obtained using the claimed method to treat contact hypersensitivity would indicate to one of skill in the art that the method of the claimed

invention could also be used for the treatment and/or prophylaxis of the above-identified disorders. In light of these, the specification is enabled for the treatment and/or prophylaxis of disorders selected from the group consisting of psoriasis, rheumatoid arthritis, scleroderma, lupus, diabetes mellitus, organ rejection, miscarriage, multiple sclerosis, inflammatory bowel disease, atherosclerosis and graft versus host disease, using apoptotic bodies.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Double Patenting

The Examiner's provisional rejection of claim 11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/866,569 (hereinafter the '569 application), is respectfully traversed. Applicants note that claim 11 is now embodied in the newly presented claims 19-30.

Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is not patently distinct from the subject matter claimed. Any rejection based on obviousness-type double patenting should make clear (1) the difference between the inventions defined by the conflicting claims and (2) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim is an obvious variation of the invention defined in a claim in the patent. *See* MPEP § 804.

The Examiner contends that although the conflicting claims are not identical, they are not patentably distinct from claim 11 of the '569 application because they both recite the use of apoptotic bodies in the treatment of inflammatory bowel disease, atherosclerosis and graft versus host disease. Initially, applicants note that canceled claim 11 in the present application and claim 11 in the '569 application are dependent claims, and dependent claims include every limitation of the claim from which it depends. *See* MPEP 608.01(n). As noted, claim 11 has been canceled, and its subject matter combined with previous claim 1 to arrive at new claim 19. New claim 19 is directed to a method for treatment or prophylaxis of T-cell-mediated or inflammatory disorders, while in the '569 application, claims 1 and 2 (from which claim 11 depends) are directed to methods of treatment or prophylaxis of medical disorders resulting from endothelial dysfunction. In point of fact, the Examiner has not rejected the previously presented independent claims over each other in the copending applications. Accordingly, the rejection, as applied to the newly presented claims, is improper because the claims are patentably distinct as they are directed to treating different disorders.

In light of these remarks, applicants respectfully request withdrawal of this provisional double patenting rejection.

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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